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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,520	12/21/2001	Jacobus M. Lemmens	ADP-019US	2171

38427 7590 07/28/2004

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,520	LEMMENS ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4-5-04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10, 12, 35- 52* is/are pending in the application.

4a) Of the above claim(s) *44-46,50 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12,35-43,47-49 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The filing of RCE dated 4-5-04 and the declaration dated 4-16-04 are acknowledged.

1. Newly submitted claims 44-46 and 50-51 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally presented claims are drawn to tablets containing a single active agent, that is, amlodipine whereas the newly presented claims are drawn to a combination of two active agents and therefore, deemed to be a distinct invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44-46 and 50-51 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims included in the prosecution are 1-10, 12, 35-43, 47-49 and 52.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 recites the negative limitation, "said crystalline amlodipine free base is not Form II crystalline amlodipine free base". If it

is not, then what is the nature of the base? The examiner suggests naming the specific form instead of a negative limitation.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-10, 12, 35-37, 39-43, and 47-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,680,334. Although the conflicting claims are not identical, they are not patentably distinct from each other because patented claims are drawn to same crystalline free base and a combination of pharmaceutically acceptable carriers and the nature of the claimed composition is disclosed in the specification as tablets which are prepared by using microcrystalline cellulose and calcium phosphate; the patented claim 2 is drawn to method of treating both hypertension and ischemic heart disease therefore, instant claims reciting tablets and method of treatment are obvious variants and are included in the patented claims.

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claim 52 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim1 of prior U.S. Patent No. 6,680,334. This is a double patenting rejection.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-2, 7-10, 12, 43, 47-49 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Young (6,057,344).

Young discloses tablet formulations containing crystalline amlodipine and a method of treating hypertension (note abstract, col.

10, line 65, Examples 4 and 8 and claims). Young does not disclose specifically the nature of the crystalline form, that is, form I or II. In the absence of showing otherwise, it is deemed that instant crystalline forms and the mixtures are deemed to be included in Young's teachings.

Claim Rejections - 35 USC 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in

section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the

manner in which the invention was made.

11. Claims 1-10, 12, 35-43, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable Over Young cited above.

The teachings of Young have been discussed above. What are lacking in Young are the teachings of the two crystalline forms or a mixture of these forms for tabletting.

However, since the nature of crystallinity is the property of a compound, in the absence of showing otherwise, it is deemed obvious to one of ordinary skill in the art that Young's crystalline preparations of amlodipine would contain these forms. Although Young does not use microcrystalline cellulose in the tablet preparations depicted in example 8, it would have been obvious to use microcrystalline cellulose since Young advocates the use of this compound on col. 11, line 44. Although Young does not specifically teach calcium hydrogen phosphate, he is suggestive of use of various carriers, diluents, granulating agents and binders on the same column and therefore, the use of a specific carrier or a granulating agent is deemed to be within the skill of the art.

12. Claims1-10, 12, 35-43 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5, 155, 120 to Lazar et al in combination with Davison cited and as set forth in the previous action.

Applicant's arguments and the declaration have been fully considered, but are not found to be persuasive. Applicant argues that Lazar generically teaches the use of amlodipine and its salts for treating congestive heart failure and a composition containing amlodipine free base was not made or used in Lazar. This argument is not found to be persuasive since Lazar is suggestive of the use of the free base and applicant has not shown any unexpected results obtained by using the crystalline forms of the base as opposed to presumed amorphous base. In this context, the declaration submitted by applicant has been carefully evaluated, but was not found to be persuasive. First of all, the declaration is unsigned. Secondly, applicant compares the

three forms of crystalline forms with amorphous base with a specific combination, that is, in combination with specific amounts of microcrystalline cellulose and calcium sulfate dehydrate. However, the independent claims are generic and recite no ingredients at all (none of the claims recite this specific combination) and there is no evidence to indicate that tablets cannot be prepared using amorphous base in combination with other art known tabletting excipients. Furthermore, according to the results presented in the table, crystalline form II shows a stickiness of 2.93 compared to the other two forms and appear to leave more residue than that claimed in instant claim 2. Finally, it is interesting to note that on page 5 of the specification, applicant states, "the amlodipine free base can be of any form including crystalline form 1, crystalline form 11, or amorphous." This statement appears to be contradictory to the results in the table, which show that amorphous base cannot form tablets at all. This rejection is deemed to be applicable since the new claim 43 is drawn to composition containing amlodipine free base and at least one pharmaceutically acceptable excipients.

13. Claims 1-10, 12, 35-43, 47-49 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5, 155, 120 to Lazar et al in combination with Young cited above.

The teachings of Lazar et al and Young have been discussed above. What are lacking in Lazar et al are the teachings of the use of microcrystalline cellulose and other excipients for the preparation of the tablets and that the form of the base be crystalline. The use of the crystalline form of amlodipine and microcrystalline cellulose and other known excipients in Lazar et al would have been obvious to one of ordinary skill in the

art with a reasonable expectation of success, since Young teaches that one can prepare tablets of amlodipine using crystalline base, microcrystalline cellulose and other excipients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G S Kishore

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK